510(k) Summary

OCT 10 2006

(As Required By 21 CFR 807.93) K061417

PreMarket Notification Summary

See Related Information

A 510(k) summary has been selected in lieu of a 510[k] statement.

Trade Name - GENICON Electrosurgical Instrumentation

Common Name - Electrosurgical Instrumentation

Classification Name - Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400, Product Code GEI)

Legally Marketed Device - Ethicon ENDOPATH (K984240)

Device Description - The GENICON disposable electrosurgical instruments are single use sterile instruments made from biocompatible plastic and stainless steel with a working length of 33cm. Current may be supplied by an approved electrosurgical generator which provides the ability for the coagulation of tissue when used with an appropriate ground electrode.

Intended Use - GENICON Disposable Electrosurgical Instrumentation is indicated for use in endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.

Technological Characteristics - The technological characteristics of the new device are the same as the predicate device.

Performance – There are no mandatory performance standards or special controls in existence for this device at the date of submittal. GENICON electrosurgical instruments were designed to meet the following voluntary standards:

AAMI/ANSI HF18:2001, Electrosurgical Devices

IEC 60601-2-2:2000, Medical electrical equipment - Particular requirements for the safety of high frequency surgical equipment

EN 12011:1998, Instrumentation to be used in association with non-active surgical implants - General requirements

ISO 7153-1:1991, Surgical Instruments -- Metallic Materials -- Part 1: Stainless Steel

ISO 4957:1999, Tool Steels

EN 868-1:1997, Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods

EN 552:1994, Sterilization of medical devices - Validation and routine control of sterilization by irradiation

Conclusion - Based on the indications for use and technological characteristics, we conclude that the new device is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Genicon
% Mr. Gary Haberland
6869 Stapoint Court, Suite 114
Winter Park, Florida 32792

OCT 10 2006

Re: K061417
Trade/Device Name: Genicon Disposable Electrosurgical Instrumentation
Regulation Number: 21 CFR 878.4400
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: GEI
Dated: September 13, 2006
Received: September 14, 2006

Dear Mr. Haberland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Indications for Use

510(k) Number (if known): **K061417**

Device Name: **Genicon Disposable Electrosurgical Instrumentation**

Indications for Use:

Endoscopic surgical procedures. It is a family of instruments which includes graspers, dissectors, and scissors, which are intended to be used to grasp, manipulate, cut, and cauterize soft tissue.

Target population definition

Patients requiring laparoscopic surgical intervention where use of an electro-surgical cutting, manipulating, and/or coagulating device is indicated.

Anatomical sites

Where laparoscopic surgical techniques are indicated, but not for fallopian tube sterilization.

Prescription Use YES ☒ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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